

A.L. 338 ta' l-2005

**ATT DWAR IS-SIGURÀ FL-IKEL
(KAP. 449)**

**Regolamenti ta' l-2005 li jemendaw ir-Regolamenti dwar
Materjali li jiġu f'Kuntatt ma' Ogġetti ta' l-Ikel**

BIS-SAHHA tas-setgħat motgħtija bl-artikolu 10 ta' l-Att dwar is-Sigurtà fl-Ikel, il-Ministru tas-Sahha, l-Anzjani u Kura fil-Komunità għamel dawn ir-regolamenti li ġejjin:-

1. It-titolu ta' dawn ir-regolamenti hu **Regolamenti ta' l-2005 li jemendaw ir-Regolamenti dwar Materjali li jiġu f'Kuntatt ma' Ogġetti ta' l-Ikel**, u għandhom jinqraw u jiftiehm u bhala haġa wahda mar-Regolamenti ta' l-2003 dwar Materjali li jiġu f'Kuntatt ma' Ogġetti ta' l-Ikel, hawn aktar 'il quddiem imsejhin "ir-regolamenti prinċipali".

Titolu.

A.L. 138 ta' l-2003.

2. Dawn ir-regolamenti jimplementaw il-provvedimenti tad-Direttiva tal-Kummissjoni 2004/19/KE ta' l-1 ta' Jannar, 2004.

Skop.

3. Fir-Raba' Skeda li tinsab mar-regolamenti prinċipali, minflok it-titolu "Registered Cellulose Film" fit-test Inġliż ta' daww ir-regolamenti, għandu jidhol it-titolu "Regenerated Cellulose Film".

Jemenda r-Raba' Skeda li tinsab mar-regolamenti prinċipali.

4. Minflok il-Hames Skeda li tinsab mar-regolamenti prinċipali għanda tidhol din l-Iskeda li ġejja:-

Jissostitwixxi l-Hames Skeda li tinsab mar-regolamenti prinċipali.

"IL-HAMES SKEDA

Ogġetti tal-plastik

1. Din l-Iskeda fiha provvedimenti speċifici fis-sens tat-tifsira tar-regolament 4.

2. Din l-Iskeda għandha tapplika għal materjali u ogġetti tal-plastik u b'hejje tagħhom li:

a) huma magħmulin eskusivament mill-plastik; jew

b) huma komposti minn żewġ saffi jew aktar ta' materjali, kull wiehed minnhom magħmul eskusivament mill-plastik, li huma

marbutin flimkien b'adeżivi jew b'xi mezz iehor, li, fl-istat tal-prodott lest, huma maħsubin biex jiġu f'kuntatt ma' oġġetti ta' l-ikel u li huma maħsubin għal dak l-iskop.

3. Għall-finijiet ta' din l-Iskeda, 'plastiki' għandha tfisser il-komposti makromolekulari organici li jissawru bil-polimerizzazzjoni, polikondensazzjoni, poliaddizzjoni jew b'xi proċess iehor simili minn molekuli ta' piż molekulari aktar baxx jew b'bidla kimika ta' makromolekulari ta' din ix-xorta. Iżda dawn li ġejjin m'għandhomx jitqiesu bhala 'plastiki':

a) Film taċ-ċellulosi riġenerat verniċjat jew mhux verniċjat, kopert mir-Raba' Skeda;

b) Elastomeri u lasktu naturali u sintetiku;

ċ) Karta u kartunċin, kemm jekk modifikati kemm jekk biż-żjieda ta' plastiki;

d) Kisi għas-superfiċji mehud minn:

- Xama' tal-parafin, inklużi xama' tal-parafin sintetici, u/jew xama' mikrokristallin,

- Tahlitiet tax-xema' elenkati fl-ewwel inċiż mħalltin flimkien u/jew ma' plastiki,

e) Reżini *ion-exchange*;

f) *Silicones*.

4. Din l-Iskeda ma għandhiex tapplika għal materjali u oġġetti komposti minn żewġ saffi jew aktar, li wahda jew aktar minnhom m'hix magħmula eskusivament minn plastiki, ukoll jekk dik maħsuba biex tiġi f'kuntatt dirett ma' oġġetti ta' l-ikel tkun magħmula eskusivament minn plastiki.

5. Materjali u oġġetti tal-plastik ma għandhomx jittrasferixxu l-kostitwenti tagħhom għall-oġġetti ta' l-ikel fi kwantitajiet li jaqbzu l-10 milligrammi kull deċimetru kwadru ta' arja tas-superfiċi ta' materjal jew oġġett (mg/dm^2) (limitu ta' migrazzjoni totali). Madanakollu dan il-limitu għandu jkun 60 milligramm tal-kostitwenti mitfughin 'il barra kull kilogram ta' oġġett ta' l-ikel (mg/kg) fil-każijiet li ġejjin:

a) Ogġetti li huma kontenituri jew li jistgħu jitqiesu bhala kontenituri jew li jistgħu jimtlew, li jesgħu inqas minn 500 millilitru (ml) jew mhux aktar minn 10 litri (l);

b) Ogġetti li jistgħu jimtlew u li mhux prattikabbli li ssir stima ta' l-arja tas-superfici tagħhom li tiġi f'kuntatt ma' ogġetti ta' l-ikel;

c) Tappijiet, gaskets, *stoppers* u apparat simili użat biex jagħlaq.

6. Dawk il-monomeri u sustanzi primarji biss elenkati fit-Tieni Anness ma' din l-Iskeda, Taqsima A jistgħu jintużaw għall-manifattura ta' materjali u ogġetti tal-plastik soġġetti għar-restrizzjonijiet speċifikati.

7. Il-listi li jidhru fit-Tieni Anness ma' din l-Iskeda, Taqsimiet A u B, għadhom ma jinkludux monomeri u sustanzi primarji użati biss fil-manifattura ta':

a) kisjiet ta' superfiċi mehudin minn prodotti tar-reżina jew prodotti polimerizzati f'forma likwida, ta' trab jew bit-tixrid, bħalma huma verniċi, *lacquers*, żebgħat, eċċ.,

b) reżini epossidiċi,

c) adeżivi u sustanzi li jgħinu l-adeżjoni,

d) linek ta' l-istampar.

8. Lista ta' additivi li jistgħu jintużaw għall-manifattura ta' materjali u ogġetti tal-plastik, flimkien mar-restrizzjonijiet u/jew speċifikazzjonijiet dwar l-użu tagħhom, tinsab fit-Tielet Anness ma' din l-Iskeda.

9. Fil-każ ta' l-additivi fit-Tielet Anness ma' din l-Iskeda, Taqsima B, il-verifika ta' konformità tal-limiti ta' migrazzjoni speċifika f'simulant D jew f'media ta' test ta' testijiet sostituti kif imniżżel f'paragrafu 6 tas-Sitt Skeda u f'paragrafu 2 tas-Seba' Skeda japplikaw sa mill-1 ta' Lulju, 2006.

10. Il-listi fit-Tielet Anness ma' din l-Iskeda, Taqsimiet A u B għad ma jinkludux l-additivi li ġejjin:

a) Additivi wżati biss fil-manifattura ta':

- kisjiet ta' superfiċi mehudin minn prodotti tar-reżina jew prodotti polimerizzati f' forma likwida, ta' trab jew bit-tixrid, bħalma huma verniċi, *lacquers*, żebgħat,
- reżini epossidiċi,
- adeżivi u sustanzi li jghinu l-adeżjoni,
- linek ta' l-istampar.

b) Koloranti

ċ) Solventi.

11. Persuna li jkollha interess li tinkludi fil-lista msemmija f'paragrafu 8 xi additiv, li huwa diġà fis-suq f'wiehed jew aktar Stati Membri, għanda tippreżenta evalwazzjoni tad-*data* fuq is-sigurtà tagħha lill- *European Food Safety Authority* mhux aktar tard mit-13 ta' Diċembru, 2006. Meta jiġi biex jippreżenta l-informazzjoni mehtieġa, l-applikant għandu jikkonsulta d-dokument "*Guidelines of the European Food Safety Authority for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorization*".

12. Jekk waqt l-eżami ta' l-informazzjoni msemmija f'paragrafu 11, l-awtorità *European Food Safety Authority* isaqsi għall-informazzjoni supplementari, l-additiv jistà jibqà jkun soġġett għall-liġijiet nazzjonali sakemm dik l-awtorità tagħti l-opinjoni tagħha, iżda dik l-informazzjoni għandha tiġi ppreżentata fi żmien limitu speċifikat mill-awtorità.

13. Huma biss dawk il-prodotti mehudin b'fermentazzjoni batterjoloġika li huma elenkati fir-Raba' Anness ma' din l-Iskeda li jistgħu jintużaw f'kuntatt ma' oġġetti ta' l-ikel.

14. L-additivi msemmija f'paragrafu 8, li huma awtorizzati bħala additivi fl-ikel bid-Direttiva tal-Kummissjoni 89/107/KEE jew saporiti bid-Direttiva tal-Kummissjoni 88/388/KEE ma għandhomx jgħaddu għal ġo:

a) Ikel fi kwantitajiet li għandom funzjoni teknoloġika fl-ikel finali;

b) Ikel li l-użu tiegħu hu awtorizzat bħala additivi fl-ikel jew saporiti, bi kwantità li hi aktar mir-restrizjonijiet li hemm provdut dwarhom fid-Direttiva 89/107/KEE jew fid-Direttiva

88/388/KEE jew f'paragrafu 8 ta' din l-Iskeda, skond liema tkun l-inqas;

ċ) Ikel li l-użu tiegħu mhux awtorizzat bhala additivi fl-ikel jew saporiti, f'kwantitajiet oghla mir-restrizzjonijiet li hemm provdut dwarhom f'paragrafu 8 ta' din l-Iskeda.

15. Fl-istadji tal-bejgħ, minbarra dak tal-bejgħ bl-imnut, il-materjali u oġġetti tal-plastik li huma mahsuba biex jitqieghdu f'kuntatt ma' oġġetti ta' l-ikel u li ghandhom additivi msemija f'paragrafu 14, ghandu jkollhom magħhom dikjarazzjoni bil-miktub bl-informazzjoni msemija f'paragrafu 24 (b).

16. B'deroga mill-paragrafu 14, meta s-sustanzi msemija f'punt (a) tal-paragrafu 14 huma użati bhala komponenti attivi ta' materjal attiv li huwa mahsub biex jigi f'kuntatt ma' l-ikel, dawn jistgħu jkunu soġġetti għal disposizzjonijiet nazzjonali.

17. Speċifikazzjonijiet ġenerali relatati ma' oġġetti u materjali tal-plastik huma mnizzlin fil-Hames Anness ma' din l-Iskeda, Parti A. Speċifikazzjonijiet ohra relatati ma' xi sustanzi li jidhru fit-Tieni, it-Tielet u r-Raba' Annessi huma mnizzlin fil-Hames Anness ma' din l-Iskeda, Parti B.

18. It-tifsira tan-numri bejn parentesi li jidhru fil-kolonna 'Restrizzjonijiet u/jew speċifikazzjonijiet' hija mfissra fis-Sitt Anness ma' din l-Iskeda.

19. Il-limiti ta' migrazzjoni speċifika fil-lista mnizzlin fit-Tieni u t-Tielet Annessi ma' din l-Iskeda huma espressi f'mg/kg. Izda dawn il-limiti huma espressi f'mg/dm² fil-każijiet li ġejjin:

a) Oġġetti li huma kontenituri jew li jistgħu jitqiesu bhala kontenituri jew li jistgħu jimtlew, li jesghu inqas minn 500 ml jew aktar minn 10 litri;

b) Folji, film jew materjal jew oġġetti ohra li ma jistgħux jimtlew jew li m'hux prattikabli li ssir stima tar-relazzjoni bejn l-arja tas-superfici ta' tali materjali u l-kwantità ta' oġġetti ta' l-ikel li jigu f'kuntatt magħha.

F'dawk il-każijiet, il-limiti mnizzlin fit-Tieni u t-Tielet Annessi ma' din l-Iskeda, espressi f'mg/kg, ghandhom ikunu diviżi bil-fattur ta' qlib konvenzjonali 6 biex jigu espressi f'mg/dm².

20. Il-verifika ta' konformità mal-limiti ta' migrazzjoni ghandha ssir skond id-disposizzjonijiet mnizzlin fis-Sitt u s-Seda' Skedi li jinsabu ma' dawn ir-regolamenti u d-disposizzjonijiet ulterjuri mnizzlin fl-Ewwel Anness ma' din l-Iskeda.

21. Il-verifika ta' konformità mal-limiti ta' migrazzjoni speċifiċi li hemm provdut dwarha fil-paragrafu 20 ma ghandhiex tkun obbligatorja, jekk il valur tal-migrazzjoni totali dterminat jimplika li l-limiti ta' migrazzjoni speċifiċi msemija f'dak il-paragrafu ma jkunux nqabzu.

22. Il-verifika ta' konformità mal-limiti ta' migrazzjoni speċifiċi li hemm provdut dwarha fil-paragrafu 20 ma ghandhiex tkun obbligatorja jekk jista' jkun stabbilit li, meta wiehed jassumi migrazzjoni kompleta tas-sustanza residwa fil-materjali jew oġġetti, ma tistax taqbez il-limiti speċifiċi ta' migrazzjoni.

23. Il-verifika ta' konformità mal-limiti ta' migrazzjoni speċifiċi li hemm provdut dwarha fil-paragrafu 20 tista' tiġi żgurata bid-determinazzjoni tal-kwantità ta' sustanza fil-materjal jew oġġett lest sakemm relazzjoni bejn dik il-kwantità u l-valur tal-migrazzjoni speċifika tas-sustanza tkun ġiet stabbilita jew b'esperimentazzjoni adegwata jew bl-applikazzjoni tal-mudelli ta' diffużjoni rikonoxxuti b'mod ġenerali u bażati fuq evidenza xjentifika. Biex wiehed juri li materjal jew oġġett ma jkunx konformi, tkun obbligatorja l-konferma tal-valur ta' migrazzjoni smat b'ittestjar sperimentali.

24. Fl-istadji tal-bejgh minbarra dak tal-bejgh bl-imnut, il-materjali u oġġetti tal-plastik li huma mahsuba biex jitqieghdu f'kuntatt ma' oġġetti ta' l-ikel ghandu jkollhom magħhom dikjarazzjoni bil-miktub, li ghandha:

a) Tkun skond ir-regolament 7.5

b) Tipprovdi, għal sustanzi li huma soġġetti għall-restrizzjonijiet fl-ikel, informazzjoni adegwata mehuda minn *data* sperimentali jew kalkolu teoretiku fuq il-livell ta' migrazzjoni speċifiċi tagħhom u, fejn ikun adatt, kriterji ta' purità skont id-Direttiva tal-Kummissjoni 95/31/KE, 95/45/KE u 2002/82/KE li jwasslu lil dak li jgħamel użu min dawn il-materjali u oġġetti biex ikun konformi mad-dispożizzjonijiet tal-Komunità relavanti jew, fin-nuqqas tagħhom, ma' disposizzjonijiet nazjonali applikabli għall-ikel.

PARTI I

DISPOSIZZJONIJIET ULTERJURI APPLIKABBLI FIL-VERIFIKA TAL-KONFORMITÀ MAL-LIMITI TA' MIGRAZZJONI

Disposizzjonijiet Ġenerali

1. Meta tqabbel ir-rizultat tat-testijiet ta' migrazzjoni speċifikati fis-Sitt Skeda, il-gravità speċifika tas-simulanti kollha għandha tittiehed konvenzjonalment bhala 1. Milligrammi ta' sustanza/sustanzi mitfughin 'il barra minn kull litru ta' simulant (mg/l) għalhekk jiġu jikkorrispondu numerikament għal milligrammi ta' sustanza/sustanzi mitfughin 'il barra minn kull kilogram ta' oġġett ta' l-ikel.
2. Meta t-testijiet ta' migrazzjoni isiru fuq kampjuni meħudin mill-materjal jew oġġetti jew fuq kampjuni manifturati apposta, u l-kwantitajiet ta' oġġetti ta' l-ikel jew simulant imqegħdin f'kuntatt mal-kampjun jiddifferixxu minn dawk użati fil-kondizzjonijiet attwali li fihom il-materjal jew oġġett kien użat, ir-rizultati miksuba għandhom ikunu kkorreġuti bl-applikazzjoni tal-formola li ġejja:

$$M = \frac{m \times a_2}{a_1 \times q} \times 1000$$

Fejn:

M hija mmigrazzjoni f' mg/kg;

M hija l-massa f' mg ta' sustanzi mitfughin 'il barra mill kampjun kif determinat mit-test ta' migrazzjoni;

a_1 hija l-arja tas-superfici f' dm² tal-kampjun f'kuntatt ma' l-oġġetti ta' l-ikel jew simulant waqt it-test ta' migrazzjoni;

a_2 hija l-arja tas-superfici f' dm² tal-materjal jew oġġett fil-kondizzjonijiet ta' użu reali;

q hija l-kwantità fi grammi ta' oġġett ta' l-ikel f'kuntatt mal-materjal jew oġġett fil-kondizzjonijiet ta' użu reali.

3. Id-determinazzjoni tal-migrazzjoni ssir fuq il-materjal jew oġġett jew, jekk dan m'hux prattikabbli, bl-użu ta' kampjuni meħudin mill-materjal jew oġġett jew, fejn hu adatt, kampjuni rappreżentattivi ta' dan il-materjal jew oġġett. Il-kampjun għandu jitqiegħed f'kuntatt ma' l-oġġett ta' l-ikel jew simulant f'manjiera li tirrappreżenta l-kondizzjonijiet ta' kuntatt fl-użu attwali. Għal dan l-iskop, it-test għandu jsir b'mod li dawk il-partijiet biss li huma maħsubin biex jiġu f'kuntatt ma' oġġetti ta' l-ikel fl-użu attwali jkunu f'kuntatt ma' l-oġġett ta' l-ikel jew simulant. Din il-kondizzjoni hi partikolarment imporant fil-każ ta' materjali jew oġġetti li jkollhom diversi saffi, għal mezzi ta' għeluq, eċċ. It-test ta' migrazzjoni ta' tappijiet, *gaskets*, *stoppers* jew apparati ta' għeluq simili għandhom isiru fuq dawn l-oġġetti billi jkunu applikati mal-kontenituri li

għalihom huma maħsubin b'mod li jikkorrispondu għall-kondizzjonijiet ta' għeluq f'użu normali jew previst.

F'kull każ għandu jkun permess li wiehed juri konformità mal-limiti ta' migrazzjoni bl-użu ta' test aktar sever.

4. Skond id-disposizzjonijiet imniżżlin fil-paragrafi 20 u 23 ta' din l-Iskeda, il-kampjun ta' materjal jew oġġett jitqiegħed f'kuntatt ma' l-oġġett ta' l-ikel jew is-simulant adatt għal perjodu u f'temperatura li jintgħażlu b'referenza għall-kondizzjonijiet ta' kuntatt f'użu attwali, skond ir-regoli mnizżlin fis-Sitt u s-Seba' Skedi li jinsabu ma' dawn ir-regolamenti. Fi tmiem il-ħin preskritt, id-determinazzjoni analitika tal-kwantità totali ta' sustanzi (migrazzjoni totali) u/jew il-kwantità speċifikata ta' sustanza waħda jew aktar (migrazzjoni speċifika) mitfughin 'il barra mill-kampjun issir fuq l-oġġett ta' l-ikel jew fuq is-simulant.
5. Meta materjal jew oġġett ikun maħsub biex jiġi f'kuntatt ripetut ma' oġġett ta' l-ikel, it-test jew testijiet ta' migrazzjoni għandhom isiru tliet darbiet fuq kampjun wiehed skond il-kondizzjonijiet imniżżla fid-Sitt Skeda u kull darba għandu jittiehed kampjun ġdid ta' l-ikel jew tas-simulant jew simulanti. Il-konformità tiegħu għandha tkun verifikata fuq bażi tal-livell ta' migrazzjoni misjub fit-tielet test. Izda jekk hemm prova konklużiva li l-livell ta' migrazzjoni ma jizdiedx fit-tieni u t-tielet test, u jekk il-limitu jew limiti ta' migrazzjoni ma jinqabzux fl-ewwel test, m'hemmx għalfejn isir test ieħor.

Disposizzjonijiet speċjali relatati ma' migrazzjoni totali

6. Jekk jintużaw is-simulanti milwiema speċifikati fis-Sitt u Seba' Skedi, id-determinazzjoni analitika tal-kwantità totali ta' sustanzi mitfughin 'il barra mill-kampjun tista' ssir bl-evaporazzjoni tas-simulant u l-użin ta' dak li jibqa'. Jekk jintużaw żejt taż-żebbuġa rettifikat jew xi wiehed mis-sostituti tiegħu, tista' tintuża l-proċedura mogħtija hawn taħt.
Il-kampjun tal-materjal jew oġġett jintiżen qabel u wara l-kuntatt mas-simulant. Is-simulant assorbit mill-kampjun ikun estratt u determinat kwantitattivament. Il-kwantità ta' simulant misjuba titnaqqas mill-piż tal-kampjun imkejjeel wara kuntatt mas-simulant. Id-differenza bejn il-piżijiet inizjali u finali tirrappreżenta l-migrazzjoni totali tal-kampjun eżaminat.
Meta materjal jew oġġett u maħsub biex jiġi f'kuntatt ripetut ma' oġġetti ta' l-ikel u jkun teknikament impossibli li jsir it-test deskritt fil-paragrafu 5, modifiki għat-test huma aċċettabbli basta tista' ssir id-determinazzjoni tal-livell ta' migrazzjoni li jsir waqt it-tielet test. Waħda minn dawn il-modifiki possibli hija deskritta hawn taħt.
It-test isir fuq tliet kampjuni identiċi tal-materjal jew oġġett. Wiehed minn dawn ikun soġġett għat-test adatt u tkun determinata l-migrazzjoni totali (M_1). It-tieni u t-tielet kampjuni jkunu soġġetti għall-istess kondizzjonijiet ta' temperatura izda l-perjodu ta' kuntatt f'kull każ għandu jkun id-doppju u t-tripplu ta' dak speċifikat u tal-migrazzjoni totali determinanti f'kull każ (M_2 u M_3 , rispettivament).

Il-materjal jew l-oġġett għandu jitqies li jkun jikkonforma basta jew M_1 jew M_3 - M_2 ma jkunux jaqbu il-limitu ta' migrazzjoni totali.

7. Materjal jew oġġett li jaqbeż il-migrazzjoni totali b'ammont mhux akbar mit-tolleranza analitika msemmija hawn taht għandu għalhekk jitqies li ma jikkonformax ma' din l-Iskeda.

It-tolleranzi analitiċi li ġejjin ġew ossevati:

- 20 mg/kg jew 3 mg/dm² f'testijiet ta' migrazzjoni meta jintużaw żejt taż-żebbuġa rettifikat jew sostituti tiegħu,
- 12 mg/kg jew 2 mg/dm² f'testijiet ta' migrazzjoni meta jintużaw simulanti oħra msemmija fis-Sitt u s-Seba' Skedi.

8. Minghajr preġudizzju għad-disposizzjonijiet tal-paragrafu 7 tas-Sitt Skeda, testijiet ta' migrazzjoni li jużaw żejt taż-żebbuġa rettifikat jew sostituti tiegħu ma għandhomx isiru biex jiċċekkjaw il-konformità mal-limiti ta' migrazzjoni totali f'każijiet meta jkun hemm prova konkluziva li l-metodu analitiku speċifikat m'hux adegwat mill-aspett tekniku.

F'xi każ bħal dan, fil-każ ta' sustanzi eżenti mil-limiti ta' migrazzjoni totali jew restrizzjonijiet oħra fil-lista mogħtija fil-Parti II ta' din l-Iskeda, hu applikat limitu ta' migrazzjoni speċifiku ġeneriku ta' 60 mg/kg jew 10 mg/dm², skond il-każ. Izda t-total tal-migrazzjonijiet speċifiċi kollha ma għandux jaqbeż il-limitu ta' migrazzjoni totali.

PARTI II

LISTA TA' MONOMERI U SUSTANZI PRIMARJI OĦRA LI JISTGĦU JINTUŻAW FIL-MANIFATTURA TA' MATERJALI U OĠĠETTI TAL- PLASTIK

INTRODUZZJONI ĠENERALI

1. Din il-parti fiha l-lista ta' monomeri u sustanzi primarji oħra. Il-lista tinkludi:
 1. Sustanzi li jkunu fi proċess ta' polimerizzazzjoni, li tinkludi polikondensazzjoni, poliaddizzjoni jew kull proċess simili ieħor, fil-manifattura ta' makromolekuli,
 2. Sustanzi makromolekulari naturali jew sintetiċi użati fil-manifattura ta' makromolekuli modifikati, jekk il-monomeri jew is-sustanzi primarji meħtieġa biex jissintetizzawhom m'humieħ inklużi fil-lista,
 3. Sustanzi użati biex jimmodifikaw sustanzi naturali jew sintetiċi eżistenti.
2. Il-lista ma tinkludix l-imlieħ (inklużi mlieħ doppji u mlieħ aċidi) ta' aluminju, ammonju, kalċju, ħadid, magnesju, potassju, sodju u žingu ta' l-aċidi, fenoli u kull alkoħol awtorizzat li huma wkoll awtorizzati.
Iżda ismijiet li fihom '...aċidu/aċidi, mlieħ' jidhru fil-lista jekk l-aċidu/l-aċidi liberi korrispondenti m'humieħ imsemmija.
F'kull każ, it-tifsira tat-terminu 'mlieħ' hu 'mlieħ ta' aluminju, ammonju, kalċju, ħadid, magnesju, potassju, sodju u žingu'.
3. Il-lista wkoll ma tinkludix is-sustanzi li ġejjin għalkemm jistgħu jkunu preżenti:
 - a) Sustanzi li jistgħu jkunu preżenti fil-prodott lest bħala:
 - Impuritajiet fis-sustanzi użati,
 - Intermedji tar-reazzjoni,
 - Prodotti tad-dekomposizzjoni;
 - b) Oligomeri u sustanzi makromolekulari naturali jew sintetiċi kif wkoll it-tahlitiet tagħhom, jekk il-monomeri jew sustanzi primarji meħtieġa biex jissintetizzawhom huma inklużi fil-lista;
 - c) Tahlitiet tas-sustanzi awtorizzati.Il-materjali u oġġetti li fihom is-sustanzi indikati taħt il-punti (a), (b) u (ċ) għandhom jikkonformaw mal-ħtiġiet imsemmija fir-regolament 3.1.
4. Sustanzi għandhom ikunu ta' kwalità teknika tajba fir-rigward tal-kriterji ta' purità.
5. Il-lista fiha l-informazzjoni li ġejja:
 - Kolonna 1 (Numru ta' Referenza): in-numru ta' referenza EEC tal-materjali ta' ppakkjar tas-sustanzi fil-lista,
 - Kolonna 2 (Numru CAS): in-numru tar-Registru CAS (*Chemical Abstracts Service*),
 - Kolonna 3 (Isem): l-isem kimiku,

- Kolonna 4 (Restrizzjonijiet u/jew speċifikazzjonijiet): Dawn jistghu jinkludu:
 - Limitu ta' migrazzjoni speċifiċi (SML),
 - Il-kwantità massima permessa tas-sustanza fil-materjal jew oġġett lest (QM),
 - Il-kwantità massima permessa tas-sustanza fil-materjal jew oġġett lest espressa bħala mg kull 6 dm² tas-superfiċi f'kuntatt ma' oġġetti ta' l-ikel (QMA),
 - Kull restrizzjoni oħra msemmija speċifikatament,
 - Kul tip ta' speċifikazzjonijiet relatati mas-sustanza jew mal-polimer.
6. Jekk sustanza li tidher fil-lista bħala komposizzjoni individwali hi ukoll koperta minn terminu ġeneriku, ir-restrizzjonijiet li japplikaw għal din is-sustanza għandhom ikunu daww indikati għall-komposizzjoni individwali.
 7. Meta hemm xi inkonsistenza bejn in-numru CAS u l-isem kimiku, l-isem kimiku għandu jiehu precedenza fuq in-numru CAS. Meta hemm xi inkonsistenza bejn in-numru CAS irrapurtat f'Einacs u r-Registru CAS, għandu japplika n-numru CAS fir-Registru CAS.
 8. Numru ta' abbrevjazzjonijiet jew espressjonijiet jintużaw fil-kolonna 4 tat-tabella, li t-tifsiriet tagħhom huma kif ġej:

DL = Limitu ta' għarfien tal-metodu ta' analiżi (*detection limit*);

FP = Materjal jew oġġett lest;

NCO = *Isocyanate moiety*;

ND = ma jistax jingħaraf. Għall-finijiet ta' dawn ir-regolamenti, 'ma jistax jingħaraf' tfisser li s-sustanza ma għandhiex tinsab b'metodu ta' analiżi validat li għandu jagħrafha meta tilhaq il-limitu speċifikat ta' għarfien (DL). Jekk dan il-metodu ma jeżistix bħalissa, jista' jintuża metodu analitiku li għandu karatteristiċi adatti ta' operat meta jintlaħaq il-limitu speċifikat ta' għarfien tas-sustanza, sakemm ikun żviluppat metodu validat;

QM = Kwantità massima permessa ta' sustanza 'residwa' fil-materjal jew oġġett. Għall-finijiet ta' din l-Iskeda l-kwantità tas-sustanza fil-materjal jew oġġett għandha tkun determinata b'metodu ta' analiżi validat. Jekk dan il-metodu ma jeżistix bħalissa, jista' jintuża metodu analitiku li għandu karatteristiċi adatt ta' operat meta jintlaħaq il-limitu speċifikat ta' kif tingħaraf is-sustanza, sakemm ikun żviluppat metodu validat;

QM(T) = Kwantità massima permessa ta' sustanza 'residwa' fil-materjal jew oġġett, espressa bħala total ta' taqsimiet jew sustanza/sustanzi indikati. Għall-finijiet ta' din l-Iskeda l-kwantità tas-sustanza fil-materjal jew oġġett għandha tkun determinata b'metodu ta' analiżi validat. Jekk dan il-metodu ma jeżistix bħalissa, jista' jintuża metodu analitiku li għandu karatteristiċi adatt ta' operat

meta jintlaħaq il-limitu speċifikat ta' kif tingħaraf is-sustanza, sakemm ikun żviluppat metodu validat;

QMA = Kwantità massima permessa ta' sustanza 'residwa' fil-materjal jew oġġett lest, espressa bħala mg kull 6 dm² fis-superfiċi f'kuntatt ma' oġġetti ta' l-ikel. Għall-finijiet ta' din l-Iskeda l-kwantità tas-sustanza fis-superfiċi tal-materjal jew oġġett għandha tkun determinata b'metodu ta' analiżi validat. Jekk dan il-metodu ma jeżistix bħalissa, jista' jintuża metodu analitiku li għandu karatteristiċi adatt ta' operat meta jintlaħaq il-limitu speċifikat ta' kif tingħaraf is-sustanza, sakemm ikun żviluppat metodu validat;

QMA(T) = Kwantità massima permessa ta' sustanza 'residwa' fil-materjal jew oġġett espressa bħala mg tat-total ta' taqsimiet jew sustanza/sustanzi indikati għal kull 6 dm² fis-superfiċi f'kuntatt ma' oġġetti ta' l-ikel. Għall-finijiet ta' din l-Iskeda l-kwantità tas-sustanza fis-superfiċi tal-materjal jew oġġett għandha tkun determinata b'metodu ta' analiżi validat. Jekk dan il-metodu ma jeżistix bħalissa, jista' jintuża metodu analitiku li għandu karatteristiċi adatt ta' operat meta jintlaħaq il-limitu speċifikat ta' kif tingħaraf is-sustanza, sakemm ikun żviluppat metodu validat;

SML = Limitu ta' migrazzjoni speċifikat f'ikel jew f'simulant ta' ikel, sakemm ma jkunx speċifikat mod ieħor. Għall-finijiet ta' din l-Iskeda l-migrazzjoni speċifika tas-sustanza għandha tkun determinata minn metodu ta' analiżi validat. Jekk dan il-metodu ma jeżistix bħalissa, jista' jintuża metodu analitiku li għandu karatteristiċi adatt ta' operat meta jintlaħaq il-limitu speċifikat ta' kif tingħaraf is-sustanza, sakemm ikun żviluppat metodu validat;

SML(T) = Limitu ta' migrazzjoni speċifikat f'ikel jew f'simulant ta' ikel, espress bħala total tat-taqsimi jew sustanza/sustanzi indikati. Għall-finijiet ta' din l-Iskeda l-migrazzjoni speċifika tas-sustanza għandha tkun determinata minn metodu ta' analiżi validat. Jekk dan il-metodu ma jeżistix bħalissa, jista' jintuża metodu analitiku li għandu karatteristiċi adatt ta' operat meta jintlaħaq il-limitu speċifikat ta' kif tingħaraf is-sustanza, sakemm ikun żviluppat metodu validat.

Sezzjoni A

Lista ta' monomeri u sustanzi primarji ohra awtorizzati

Skond Sezzjoni A tat-Tieni Anness tad-Direttiva tal-Kummissjoni 2002/72/KE (OJ L 220, 15.08.2002, p. 18-58) kif emendata permezz tad-Direttivi hawn taht imsemmija:

1. Direttiva tal-Kummissjoni 2004/1/KE (OJ L 7, 13.01.2004, p. 45)
2. Direttiva tal-Kummissjoni 2004/19/KE (OJ L 71, 10.03.2004, p. 8-21)

Kopji ta' l-Anness imsemmi hawn fuq għandhom ikunu aċċessibbli għall-pubbliku ġenerali mid-Direttorat għall-Ogġetti ta' l-Ikel, Kimiċi u Kosmetiċi ta' l-Awtorità Maltija dwar l-Istandards.

Sezzjoni B

Lista ta' monomeri u sustanzi primarji ohra li jistgħu jkomplu jintużaw sakemm tittiehed deċiżjoni dwar l-inklużjoni tagħhom f'Sezzjoni A

Skond Sezzjoni B tat-Tieni Anness tad-Direttiva tal-Kummissjoni 2002/72/KE (OJ L 220, 15.08.2002, p. 18-58) kif emendata permezz tad-Direttivi hawn taht imsemmija:

1. Direttiva tal-Kummissjoni 2004/1/KE (OJ L 7, 13.01.2004, p. 45)
2. Direttiva tal-Kummissjoni 2004/19/KE (OJ L 71, 10.03.2004, p. 8-21)

Kopji ta' l-Anness imsemmi hawn fuq għandhom ikunu aċċessibbli għall-pubbliku ġenerali mid-Direttorat għall-Ogġetti ta' l-Ikel, Kimiċi u Kosmetiċi ta' l-Awtorità Maltija dwar l-Istandards.

PARTI III

LISTA MHUX KOMPLETA TA' ADDITIVI LI JISTGĦU JINTUŻAW FIL-MANIFATTURA TA' MATERJALI U OĠĠETTI TAL-PLASTIK

INTRODUZZJONI ĠENERALI

1. Din il-Parti fiha lista ta':
 - a. Sustanzi lu huma inkorporati fi plastiċi biex jaslu għal effett tekniku fil-prodott lest, inklużi 'additivi polimeriċi'. Huma maħsubin biex ikunu preżenti fl-oġġett lest;
 - b. Sustanzi użati biex jipprovdu mezz adatt li fih issir il-polimerizzazzjoni.

Għall-finijiet ta' din il-Parti, is-sustanzi msmmija f'(a) u (b) huma minhawn il-quddiem msejha bħala 'additivi'.

Għall-finijiet ta' din il-Parti, 'additivi polimeriċi' tfisser kull polimer u/jew prepolimer u/jew oligomeri li jista' jkun mizjud ma' plastiċi għal l-iskop li jaslu għal effett tekniku imma li ma jkunx jista' jintuża fin nuqqas ta' polimeri oħrajn bħala l-komponent strutturali ewlieni tal-materjali u oġġetti lesti. Huma inklużi wkoll sustanzi li jistgħu jiġu mizjuda mal-mezz li fih issir il-polimerizzazzjoni.

Il-lista ma tinkludix:

- a) Is-sustanzi li jinfluwenzaw direttament il-formazzjoni ta' polimeri;
 - b) Koloranti;
 - c) Solventi.
2. Il-lista ma tinkludix l-imlieh (inkużi mlieh doppji u mlieh aċidi) ta' aluminju, ammonju, kalċju, haċid, magnesju, potassju, sodju u zingu ta' aċidi li huma wkoll awtorizzati. Izda ismijiet li fihom '...aċidu/aċidi, mlieh' jidhru fil-lista jekk l-aċidu/l-aċidi liberi korrispondenti m'humiex imsemmija. F'każijiet bħal dawn, it-tifsira tat-terminu 'mlieh' hi 'mlieh ta' aluminju, ammonju, kalċju, haċid, magnesju, potassju, sodju u zingu'.
 3. Il-lista ma tinkludix is-sustanzi li ġejjin għalkemm jistgħu jkunu preżenti:
 - a. Sustanzi li jistgħu jkunu preżenti fil-prodott lest bħal:
 - Impuritajiet fis-sustanzi użati,
 - Intermedji tar-reazzjoni,
 - Prodotti tad-dekomposizzjoni;
 - b. Taħlitiet tas-sustanzi awtorizzati.Il-materjali u oġġetti li fihom is-sustanzi indikati f'(a) u (b) għandhom jikkonformaw mal-htigiet imsemmija fir-regolament 3.1.
 4. Sustanzi għandhom ikunu ta' kwalità teknika tajba fir-rigward tal-kriterji ta' purità.

5. Il-lista fiha l-informazzjoni li ġejja:
 - Kolonna 1 (Numru ta' Referenza): in-numru ta' referenza EEC tal-materjali ta' ppakkjar tas-sustanzi fil-lista,
 - Kolonna 2 (Numru CAS): in-numru tar-Registru CAS (*Chemical Abstracts Service*),
 - Kolonna 3 (Isem): l-isem kimiku,
 - Kolonna 4 (Restrizzjonijiet u/jew speċifikazzjonijiet): Dawn jistgħu jinkludu:
 - Limitu ta' migrazzjoni speċifiki (SML),
 - Il-kwantità massima permessa tas-sustanza fil-materjal jew oġġett lest (QM),
 - Il-kwantità massima permessa tas-sustanza fil-materjal jew oġġett lest espressa bħala mg kull 6 dm² tas-superfici f'kuntatt ma' oġġetti ta' l-ikel (QMA),
 - Kull restrizzjoni oħra msemmija speċifikatament,
 - Kul tip ta' speċifikazzjoni relatata mas-sustanza jew mal-polimer.
6. Jekk sustanza li tidher fil-lista bħala kompożizzjoni individwali hi ukoll koperta minn terminu ġeneriku, ir-restrizzjonijiet li japplikaw għal din is-sustanza għandhom ikunu dawk indikati għall-komposizzjoni individwali.
7. Meta jkun hemm xi inkonsistenza bejn in-numru CAS u l-isem kimiku, l-isem kimiku għandu jieħu preċedenza fuq in-numru CAS. Meta hemm xi inkonsistenza bejn in-numru CAS irrapurtat f'Einacs u r-Registru CAS, għandu japplika n-numru CAS fir-Registru CAS.

Sezzjoni A

Lista mhux shiha ta' additivi armonizzati b'mod shih fl-livell ta' Komunità

Skond it-Tielet Anness mad-Direttiva tal-Kummissjoni 2002/72/KE (OJ L 220, 15.08.2002, p. 18-58) kif emendata permezz tad-Direttivi hawn taht imsemmija:

1. Direttiva tal-Kummissjoni 2004/1/KE (OJ L 7, 13.01.2004, p. 45)
2. Direttiva tal-Kummissjoni 2004/19/KE (OJ L 71, 10.03.2004, p. 8-21)

Kopji ta' l-Anness imsemmi hawn qabel għandhom ikunu aċċessibbli għall-pubbliku ġenerali mid-Direttorat għall-Ogġetti ta' l-Ikel, Kimiċi u Kosmetiċi ta' l-Awtorità Maltija dwar l-Istandards.

Sezzjoni B

Lista mhux shiha ta' additivi li hemm referenza għalihom f'paragrafu 9 ta' din l-Iskeda

Skond it-Tielet Anness mad-Direttiva tal-Kummissjoni 2002/72/KE (OJ L 220, 15.08.2002, p. 18-58) kif emendata permezz tad-Direttivi hawn taht imsemmija:

1. Direttiva tal-Kummissjoni 2004/1/KE (OJ L 7, 13.01.2004, p. 45)
2. Direttiva tal-Kummissjoni 2004/19/KE (OJ L 71, 10.03.2004, p. 8-21)

Kopji ta' l-Anness imsemmi hawn qabel għandhom ikunu aċċessibbli għall-pubbliku ġenerali mid-Direttorat għall-Ogġetti ta' l-Ikel, Kimiċi u Kosmetiċi ta' l-Awtorità Maltija dwar l-Istandards.

PARTI IV

PRODOTTI MIKSUBIN PERMEZZ TA' FERMENTAZZJONI BATTERJOLOĠIKA

Skond ir-Raba' Anness mad-Direttiva tal-Kummissjoni 2002/72/KE (OJ L 220, 15.08.2002, p. 18-58) kif emendata permezz tad-Direttivi hawn taht imsemmija:

1. Direttiva tal-Kummissjoni 2004/1/KE (OJ L 7, 13.01.2004, p. 45)
2. Direttiva tal-Kummissjoni 2004/19/KE (OJ L 71, 10.03.2004, p. 8-21)

Kopji ta' l-Anness imsemmi hawn qabel għandhom ikunu aċċessibbli għall-pubbliku ġenerali mid-Direttorat għall-Ogġetti ta' l-Ikel, Kimiċi u Kosmetiċi ta' l-Awtorità Maltija dwar l-Istandards.

PARTI V

SPEĊIFIKAZZJONIJIET

Parti A: Speċifikazzjonijiet ġenerali

Il-materjal u ogġett manifatturat bl-użu ta' isoċjanati aromatiċi jew koloranti preparati bid-*diazo-coupling*, ma għandhomx jittfghu 'ilbarra amini aromatiċi primarji (espressi bħala anilina) fi kwantità li tista' tingħaraf (DL = 0,02 mg/kg ta' ikel jew stimulant ta' ikel, inkluża tolleranza analitika). Izda l-valuri ta' migrazzjoni ta' amini aromatiċi primarji mnizzlin f'din l-Iskeda huma esklużi minn din ir-restrizzjoni.

Parti B: Speċifikazzjonijiet oħra

Skond Parti B tal-Hames Anness mad-Direttiva tal-Kummissjoni 2002/72/KE (OJ L 220, 15.08.2002, p. 18-58) kif emendata permezz tad-Direttivi hawn taht imsemmija:

1. Direttiva tal-Kummissjoni 2004/1/KE (OJ L 7, 13.01.2004, p. 45)
2. Direttiva tal-Kummissjoni 2004/19/KE (OJ L 71, 10.03.2004, p. 8-21)

Kopji ta' l-Anness imsemmi hawn qabel għandhom ikunu aċċessibbli għall-pubbliku ġenerali mid-Direttorat għall-Ogġetti ta' l-Ikel, Kimiċi u Kosmetiċi ta' l-Awtorità Maltija dwar l-Istandards.

PARTI VI

**NOTI RELATATI MAL-KOLONNA 'RESTRIZZJONIJIET U/JEW
SPECIFIKAZZJONIJET'**

Skond is-Sitt Anness tad-Direttiva tal-Kummissjoni 2002/72/KE (OJ L 220, 15.08.2002, p. 18-58) kif emendata permezz tad-Direttivi hawn taht imsemmija:

1. Direttiva tal-Kummissjoni 2004/1/KE (OJ L 7, 13.01.2004, p. 45)
2. Direttiva tal-Kummissjoni 2004/19/KE (OJ L 71, 10.03.2004, p. 8-21)

Kopji ta' l-Anness imsemmi hawn qabel għandhom ikunu aċċessibbli għall-pubbliku ġenerali mid-Direttorat għall-Ogġetti ta' l-Ikel, Kimiċi u Kosmetiċi ta' l-Awtorità Maltija dwar l-Istandards.”.

L.N. 338 of 2005

**FOOD SAFETY ACT
(CAP. 449)**

**Materials in Contact with Foodstuffs (Amendment) Regulations,
2005**

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister of Health, the Elderly and Community Care has made the following regulations:-

1. The title of these regulations is the Materials in Contact with Foodstuffs (Amendment) Regulations, 2005, and they shall be read and construed as one with the Materials in Contact with Foodstuffs Regulations, 2003, hereinafter referred to as “the principal regulations”. Citation.
L.N. 138 of 2003.
2. These regulations implement the provisions of Commission Directive 2004/19/EC of the 1st March, 2004. Scope.
3. In the Fourth Schedule to the principal regulations, for the title “Registered Cellulose Film” in the English version thereto, it shall be substituted by the title “Regenerated Cellulose Film”. Amends the Fourth
Schedule to the
Principal
Regulations.
4. For the Fifth Schedule to the principal regulations, there shall be substituted the following:- Substitutes the Fifth
Schedule to the
principal
regulations.

“FIFTH SCHEDULE

Plastics

1. This Schedule contains specific provisions within the meaning of regulation 4.
2. This Schedule shall apply to plastic materials and articles and parts thereof:
 - a) consisting exclusively of plastics; or
 - b) composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means, which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose.

3. For the purposes of this Schedule, 'plastics' means the organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Other substances or matter may be added to such macromolecular compounds. However, the following shall not be regarded as 'plastics':

- a) Varnished or unvarnished regenerated cellulose film, covered by the Fourth Schedule;
- b) Elastomers and natural and synthetic rubber;
- c) Paper and paperboard, whether modified or not or by the addition of plastics;
- d) Surface coatings obtained from:
 - Paraffin waxes, including synthetic paraffin waxes, and/or microcrystalline waxes,
 - Mixtures of the waxes listed in the first indent with each other and/or with plastics,
- e) Ion-exchange resins;
- f) Silicons.

4. This Schedule shall not apply to materials and articles composed of two or more layers, one or more of which does not consist exclusively of plastics, even if the one intended to come into direct contact with foodstuffs does consist exclusively of plastics.

5. Plastic materials and articles shall not transfer their consistent to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm^2) (overall migration limit). However, this limit shall be 60 milligrams of the constituents released per kilogram of foodstuff (mg/kg) in the following cases:

- a) Articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 50 millimetres (ml) and not more than 10 litres (l);
- b) Articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;

c) Caps, gaskets, stoppers or similar devices for sealing.

6. Only those monomers and other starting substances listed in the Second Annex to this Schedule, section A may be used for the manufacture of plastic materials and articles subject to the restrictions set out therein.

7. The lists appearing in the Second Annex to this Schedule, Sections A and B, do not yet include monomers and other starting substances used only in the manufacture of:

a) surface coatings obtained from resinous or polymerized products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,

b) epoxy resins,

c) adhesives and adhesion promoters,

d) printing inks.

8. A list of additives which may be used for the manufacture of plastic materials and articles, together with the restriction and/or specifications on their use, is set out in the Third Annex to this Schedule.

9. For the additives listed in the Third Annex to this Schedule, Section B, the verification of compliance with the specific migration limits in simulant D or in the test media of substitute tests as laid down in paragraph 6 of the Sixth Schedule and paragraph 2 of the Seventh Schedule shall apply from the 1st July, 2006.

10. The lists in the Third Annex to this Schedule, Sections A and B do not yet include the following additives:

a) Additives used only in the manufacture of:

- Surface coatings obtained resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints,

- Epoxy resins,

- Adhesives and adhesion promoters,

- Printing inks;

- b) Colorants;
- c) Solvents.

11. Any person interested in the inclusion in the list referred to in paragraph 8 of an additive, which is already placed on the market in one or more of the Member States, shall submit data evaluation of its safety by the European Food Safety Authority by the 31st December, 2006 at the latest. For the submission of the required data, the applicant shall consult the “Guidelines of the European Food Safety Authority for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation”.

12. If during the examination of the data referred to in paragraph 11, the European Food Safety Authority calls for supplementary information, the additive may continue to be subject to national law until the Authority has issued an opinion, provided that the information is submitted within the time limits specified by the Authority.

13. Only the products obtained by means of bacterial fermentation listed in the Fourth Annex to this Schedule may be used in contact with foodstuffs.

14. Additives referred to in paragraph 8, which are authorised as food additives by Council Directive 89/107/EEC or flavourings by Council Directive 88/388/EEC shall not migrate into:

- a) Foodstuffs in quantities having a technological function in the final foodstuffs;
- b) Foodstuffs for which their use is authorised as food additives or flavourings, in quantities exceeding the restrictions provided for in Directive 89/107/EEC or in Directive 88/388/EEC or in paragraph 8 of this Schedule, whichever is the lower;
- c) Foodstuffs for which their use is not authorised as food additives or flavourings, in quantities exceeding the restrictions set out in paragraph 8 of this Schedule.

15. At the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs and which contain additives referred to in paragraph 14, shall be accompanied by a written declaration containing the information referred to in paragraph 24 (b).

16. By way of derogation from paragraph 14, when the substances referred to in point (a) of paragraph 14 are used as active components of active food contact materials and articles, they may be subject to national provisions.

17. General specifications related to plastic materials and articles are laid down in the Fifth Annex to this Schedule, Part A. Other specifications related to some substances appearing in the Second, Third and Fourth Annexes are laid down in the Fifth Annex to this Schedule, Part B.

18. The meaning of the numbers between brackets appearing in the column 'Restrictions and/or specifications' is explained in the Sixth Annex to this Schedule.

19. The specific migration limits in the list set out in the Second and Third Annex to this Schedule are expressed in mg/kg. However, such limits are expressed in mg/dm² in the following cases:

a) Articles which are containers or are comparable to containers or which can be filled, with a capacity less than 500 ml or more than 10 litres;

b) Sheet, film or other material or articles which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact therewith.

In those cases, the limits set out in the Second and Third Annex to this Schedule, expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm².

20. Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in the Sixth and Seventh Schedules to these regulations and the further provisions set out in the First Annex to this Schedule.

21. The verification of compliance with the specific migration limits provided for in paragraph 20 shall not be compulsory, if the value of overall migration determination implies that the specific migration limits referred to in that paragraph are not exceeded.

22. The verification of compliance with the specific migration limits provided for in paragraph 20 shall not be compulsory, if it can be established that, by assuming complete migration of the residual

substance in the material or article, it cannot exceed the specific limit of migration.

23. The verification of compliance with the specific migration limits provided for in paragraph 20 may be ensured by the determination of the quantity of a substance in the finished material or article provided that a relationship between that quantity and the value of the specific migration of the substance has been established either by an adequate experimentation or by the application of generally recognised diffusion models based on scientific evidence. To demonstrate the non-compliance of a material or article, confirmation of the estimated migration value by experimental testing is obligatory.

24. At the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration, which shall:

a) Be in accordance with regulation 7.5;

b) Provide, for substances which are subject to a restriction in food, adequate information obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Commission Directives 95/31/EC, 95/45/EC and 2002/82/EC to enable the user of these materials and articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food.

PART I

FURTHER PROVISIONS APPLICABLE WHEN CHECKING COMPLIANCE WITH THE MIGRATION LIMITS**General provisions**

1. When comparing the results of the migration tests specified in the Sixth Schedule, the specific gravity of all the simulants should conventionally be assumed to 1. Milligrams of substance(s) released per litre of stimulant (mg/l) will thus correspond numerically to milligrams of substance(s) released per kilogram of simulant and, taking into account the provisions laid down in the Seventh Schedule, to milligrams of substance(s) released per kilogram of foodstuff.
2. Where the migration tests are carried out on samples taken from the material or article or on samples manufactured for the purpose, and the quantities of foodstuff or simulant placed in contact with the sample differ from those employed in the actual conditions under which the material or article is used, the results obtained should be corrected by applying the following formula:

$$M = \frac{m \times a_2}{a_1 \times q} \times 1000$$

Where:

M is the migration in mg/kg;

m is the mass in mg of substance released by the sample as determined by the migration test;

a_1 is the surface area in dm² of the sample in contact with the foodstuff or simulant during the migration test;

a_2 is the surface area in dm² of the material or article in real conditions of use;

q is the quantity in grams of foodstuff in contact with the material or article in real conditions of use.

3. The determination of migration is carried out on the material or article or, if that is impracticable, using either specimens taken from the material or article or, where appropriate, specimens representative of this material or article.
The sample shall be placed in contact with the foodstuff or simulant in a manner representing the contact conditions in actual use. For this purpose, the test shall be performed in such a way that only those parts of the sample intended to come into contact with foodstuffs in actual use will be in contact with the foodstuff or simulant. This condition is particularly important in the case of materials and articles comprising several layers, for closures, etc.
The migration testing of caps, gaskets, stoppers or similar devices for sealing must be carried out on these articles by applying them to the containers for which they are intended in a manner which corresponds to the conditions of closing in normal or foreseeable use.
It shall in all cases be permissible to demonstrate compliance with migration limits by the use of a more severe test.

4. In accordance with the provisions set out in paragraphs 20 to 23 of this Schedule, the sample of the material or article is placed in contact with the foodstuff or appropriate simulant for a period and at a temperature which are chosen by reference to the contact conditions in actual use, in accordance with the rules laid down in the Sixth and Seventh Schedules to these regulations. At the end of the prescribed time, the analytical determination of the total quantity of substances (overall migration) and/or the specific quantity of one or more substances (specific migration) released by the sample is carried out on the foodstuff or simulant.
5. Where a material or article is intended to come into repeated contact with foodstuffs, the migration test(s) shall be carried out three times on a single sample in accordance with the conditions laid down in the Sixth Schedule using another sample of the food or simulant(s) on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the migration limit(s) is (are) not exceeded on the first test, no further test is necessary.

Special provisions relating to overall migration

6. If the aqueous simulants specified in the Sixth and Seventh Schedules are used, the analytical determination of the total quantity of substances released by the sample may be carried out by evaporation of the simulant and weighing of the residue. If rectified olive oil or any of its substitutes is used, the procedure given below may be followed.

The sample of the material or article is weighed before and after contact with the simulant. The simulant absorbed by the sample is extracted and determined quantitatively. The quantity of simulant found is subtracted from the weight of the sample measured after contact with the simulant. The difference between the initial and corrected final weights represents the overall migration of the sample examined.

Where a material or article is intended to come into repeated contact with foodstuffs and it is technically impossible to carry out the test described in paragraph 5, modifications to that test are acceptable, provided that they enable the level of migration occurring during the third test to be determined. One of these possible modifications is described below.

The test is carried out on three identical samples of the material or article. One of these shall be subjected to the appropriate test and the overall migration determined (M1). The second and third samples shall be subjected to the same conditions of temperature but the period of contact shall be two and three times that specified and overall migration determined in each case (M2 and M3, respectively).

The material or article shall be deemed to be in compliance provided that either M1 or M3 - M2 do not exceed the overall migration limit.
7. A material or article that exceeds the overall migration limit by an amount not greater than the analytical tolerance mentioned below should therefore be deemed to be in compliance with this Schedule.

The following analytical tolerances have been observed:

 - 20 mg/kg or 3 mg/dm² in migration tests using rectified olive oil or substitutes,

- 12 mg/kg or 2 mg/dm² in migration tests using the other simulants referred to in the Sixth and Seventh Schedules.
8. Without prejudice to the provisions of paragraph 7 of the Sixth Schedule, migration tests using rectified olive oil or substitutes shall not be carried out to check compliance with the overall migration limit in cases where there is conclusive proof that the specified analytical method is inadequate from a technical standpoint. In any such case, for substances exempt from specific migration limits or other restrictions in the list provided in Part II of this Schedule, a generic specific migration limit of 60 mg/kg or 10 mg/dm², according to the case, is applied. However, the sum of all specific migrations determined shall not exceed the overall migration limit.

PART II

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES WHICH MAY BE USED IN THE MANUFACTURE OF PLASTIC MATERIALS AND ARTICLES

GENERAL INTRODUCTION

1. This Part contains the list of monomers or other starting substances. The list includes:
 - substances undergoing polymerisation, which includes polycondensation, polyaddition or any other similar process, to manufacture macromolecules,
 - natural or synthetic macromolecular substances used in the manufacture of modified macromolecules, if the monomers or the other starting substances required to synthesise them are not included in the list,
 - substances used to modify existing natural or synthetic substances.
2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorised acids, phenols or alcohols which are also authorised.
However, names containing '... acid(s), salts' appear in the lists if the corresponding free acid(s) is (are) not mentioned.
In each case the meaning of the term 'salts' is 'salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc'.
3. The list also does not include the following substances although they may be present:
 - (a) substances which could be present in the finished product as:
 - impurities in the substances used,
 - reaction intermediates,
 - decomposition products;
 - (b) oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or starting substances required to synthesise them are included in the list;
 - (c) mixtures of the authorised substances.The materials and articles, which contain the substances indicated under points (a), (b) and (c) shall comply with the requirements stated in regulation 3.1.
4. Substances shall be of good technical quality as regards the purity criteria.
5. The list contains the following information:
 - column 1 (Ref. No): the EEC packaging material reference number of the substances on the list,
 - column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,
 - column 3 (Name): the chemical name,
 - column 4 (Restrictions and/or specifications): These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically mentioned,
 - any type of specifications related to the substance or to the polymer.

6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.
7. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in Einescs and the CAS Registry, the CAS number in the CAS Registry shall apply.
8. A number of abbreviations or expressions are used in column 4 of the table, the meanings of which are as follows:

DL = Detection limit of the method of analysis;

FP = Finished material or article;

NCO = Isocyanate moiety;

ND = not detectable. For the purpose of these regulations 'not detectable' means that the substance should not be detected by a validated method of analysis which should detect it at the detection limit (DL) specified. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the detection limit may be used, pending the development of a validated method;

QM = Maximum permitted quantity of the 'residual' substance in the material or article. For the purpose of this Schedule the quantity of the substance in the material or article shall be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specific limit may be used, pending the development of a validated method;

QM(T) = Maximum permitted quantity of the 'residual' substance in the material or article expressed as total of moiety or substance(s) indicated. For the purpose of this Schedule the quantity of the substance in the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

QMA = Maximum permitted quantity of the 'residual' substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Schedule the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

QMA(T) = Maximum permitted quantity of the 'residual' substance in the material or article expressed as mg of total of moiety or substance(s) indicated per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Schedule the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

SML = Specific migration limit in food or in food simulant, unless it is specified otherwise. For the purpose of this Schedule the specific migration of the substance should be determined by a validated method of analysis. If such a method does not

currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;
SML(T) = Specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated. For the purpose of this Schedule the specific migration of the substances should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.

Section A

List of authorised monomers and other starting substances

As stipulated by Section A of Annex II of Commission Directive 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

Section B

List of monomers and other starting substances which may continue to be used pending a decision on inclusion in Section A

As stipulated by Section B of Annex II of Commission Directive 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

PART III

INCOMPLETE LIST OF ADDITIVES WHICH MAY BE USED IN THE MANUFACTURE OF PLASTIC MATERIALS AND ARTICLES

GENERAL INTRODUCTION

1. This Part contains the list of:
 - a. Substances which are incorporated into plastics to achieve a technical effect in the finished product, including “polymeric additives”. They are intended to be present in the finished articles;
 - b. substances used to provide a suitable medium in which polymerisation occurs.

For the purposes of this Part, the substances referred to in (a) and (b) are hereinafter referred to as “additives”.

For the purpose of this Part, “Polymeric additives” means any polymer and/or prepolymer and/or oligomer which may be added to plastics in order to achieve a technical effect but which cannot be used in absence of other polymers as the main structural component of finished materials and articles. It includes also substances which may be added to the medium in which polymerisation occurs.

The list does not include:

- a. the substances which directly influence the formation of polymers;
 - b. colorants;
 - c. solvents.
2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorised acids, phenols or alcohols which are also authorised. However, names containing ‘...acid(s), salts’ appear in the lists if the corresponding free acid(s) is (are) not mentioned. In such cases the meaning of the term ‘salts’ is ‘salts of aluminium ammonium, calcium, iron, magnesium, potassium, sodium and zinc’.
 3. The list does not include the following substances although they may be present:
 - (a) substances which could be present in the finished product such as:
 - impurities in the substances used,
 - reaction intermediates,
 - decomposition products;
 - (b) mixtures of the authorised substances.The materials and articles which contain the substances indicated in (a) and (b) shall comply with the requirements stated in regulation 3.1.
 4. Substances shall be of good technical quality as regards the purity criteria.
 5. The list contains the following information:
 - column 1 (Ref. No): the EEC packaging material reference number of the substances on the list,
 - column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,

- column 3 (Name): the chemical name,
 - column 4 (Restrictions and/or specifications). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically mentioned,
 - any type of specifications related to the substance or to the polymer.
6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.
7. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in EINECS and the CAS registry, the CAS number in the CAS registry shall apply.

Section A

Incomplete list of additives fully harmonised at Community level

As stipulated by Annex III of Commission Directive 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

Section B

Incomplete list of additives referred to in paragraph 9 of this Schedule

As stipulated by Annex III of Commission Directive 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

PART IV

PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

As stipulated by Annex IV of Commission Directive 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

PART V

SPECIFICATIONS

Part A: General Specifications

The material and article manufactured by using aromatic isocyanates or colorants prepared by diazo-coupling, shall not release primary aromatic amines (expressed as aniline) in a detectable quantity (DL = 0,02 mg/kg of food or food simulant, analytical tolerance included). However, the migration value of the primary aromatic amines listed in this Schedule are excluded from this restriction.

Part B: Other Specifications

As stipulated by Part B of Annex V of Commission Directive 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

PART VI

NOTES RELATED TO THE COLUMN 'RESTRICTIONS AND/OR SPECIFICATIONS'

As stipulated by Annex VI of Commission Directive 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.”.